REMARKS

Status of the Claims

Claims 1-3, 5 and 15-22 are currently pending in the application. Claims 1-3 and 5 stand rejected. Claims 1-3 have been amended. Claims 9-14 have been cancelled. All amendments and cancellations are made without prejudice or disclaimer. New claims 15-22 have been added. No new matter has been added by way of the present amendments. Specifically, the amendment to claim 1 is merely to address grammatical and typographical issues. The amendments to claims 2 and 3 are to address alleged indefiniteness issues. New claims 15 and 16 are supported by at least claim 3. New claim 17 is supported by the knowledge of one of skill in the art. New claims 18 and 19 are supported by at least claim 2. New claims 20 and 21 are supported by the specification at least at page 7, lines 19-24, page 8, lines 27-33, page 14, lines 30-34. New claim 22 is supported by the specification at least at pages 10-14. Reconsideration is respectfully requested.

Interview

Applicants and Applicants' representatives thank the Examiner for extending the courtesy of an interview on or about February 14, 2008. During the interview, Applicants' representative inquired about the objection to the specification. Specifically, Applicants' representative pointed out to the Examiner that no hyperlink, trademark or other objectionable material is disclosed at page 4, line 20 of the specification, as alleged in the present Office Action, at page 3. A search of the entirety of the specification also did not reveal any such objectionable disclosure. The Examiner agreed and stated that the objection was in error and should be withdrawn. However,

Applicants' representative wish to point out that they have endeavored to be completely responsive to the present Office Action and have therefore submitted herewith a Substitute Sequence Listing and CRF copy thereof in full compliance of the Sequence Rules, as discussed in further detail below.

Objections to the Specification

The Examiner states that the present application contains sequence disclosures and does not comply with the requirements for patent applications containing nucleotide sequences and/or amino acid sequences. (*See*, Office Action, at page 3, hereinafter, "Office Action").

Applicants note that this is a National Stage entry of an International Application. Upon entry of the National Stage the USPTO was supplied with a paper copy of the sequence listing. Thus, the only item missing appears to be a CRF copy of the sequence listing. Applicants submit herewith a substitute sequence listing along with a CRF copy of the substitute sequence listing, to comply with the Sequence Rules. Applicants also note that the specification has been carefully reviewed and appears to fully comply with the Rules concerning the requirement for sequence identifiers.

Therefore, enclosed herewith in full compliance with 37 C.F.R. §§1.821-1.825 is a Substitute Sequence Listing to be inserted into the specification as indicated above. The Substitute Sequence Listing in no way introduces new matter into the specification. Also submitted herewith in full compliance with 37 C.F.R. §§1.821-1.825 is a CRF copy of the Substitute Sequence Listing. The CRF copy of the Substitute Sequence Listing, file "2008-02-25 3535-0138PUS1.ST25.txt", is identical to the paper copy, except that it lacks formatting. In no

way does the paper copy nor the CRF copy of the Substitute Sequence Listing introduce new matter into the application.

The Sequence Listing is amended to identify the present application by filing date and serial number and to correct matters of form. No new matter is introduced by these amendments.

The Examiner also objects to the specification for reciting an embedded hyperlink at page 4, line 20. However, as discussed above, regarding the Interview, the Examiner has withdrawn this objection because no objectionable disclosure could be found in the specification.

Therefore, reconsideration and withdrawal of the objections to the specification are respectfully required.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 2 and 3 stand rejected under 35 U.S.C. § 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. (*See*, Office Action, at page 4). Applicants traverse the rejection as set forth herein.

The Examiner states that the claims recite informal language including "such as" and "including" and requests correction.

Although Applicants do not agree that the claims are vague or indefinite, to expedite prosecution, claims 2 and 3 have been amended herein without prejudice or disclaimer to remove the term "including" and the phrase "such as" as suggested by the Examiner.

Reconsideration and withdrawal of the indefiniteness rejection of claims 2 and 3 are respectfully requested.

Rejections Under 35 U.S.C. § 112, First Paragraph

Written Description

Claims 1-3 and 5 stand rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement. (*See*, Office Action, at pages 4-6). Applicants traverse the rejection as set forth herein.

The Examiner states that the claims encompass a large genus of CGRP derivatives, containing many possible species. (*Id.* at page 5). However, the Examiner states that the specification provides little or no support for this large number of species. (*Id.*).

Although Applicants do not agree that the present claims lack written description support, to expedite prosecution, claim 2 has been amended to remove the term "derivative."

Applicants wish to additionally point out that new claim 17 is supported by the knowledge of one of skill in the art. That is, one of skill in the art is deemed to possess the knowledge disclosed in the art through various scientific publications. For instance, the Examiner's attention is respectfully directed to the publications of Rist et al., *J. Med. Chem.*, 41(1):117-123, 1998 and Carpenter et al., *Biochem.*, 40(28):8317-8325, 2001.

Furthermore, a "patent need not teach, and preferably omits, what is well known in the art." (*See, Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1534 (Fed. Cir. 1987) and *Hybritech v. Monoclonal Antibodies*, 802 F. 2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986), cert, denied, 107 S. Ct. 1606 (1987)). Additionally, the MPEP states that, "If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met." (*See*, MPEP, at 2163, II, A, 3, (a), citing *Vas-Cath v.*

Mahurkar, 935 F.2d 155, at 1563, 19 USPQ2d 1111, at 1116 (CAFC 1991), *Martin v. Johnson*, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972), stating "'the description need not be in *ipsis verbis* [*i.e.*, "in the same words"] to be sufficient'").

Since no specific reasoning is provided for the written description rejection of claims 1, 3 and 5, these claims are believed to also be enabled as, *inter alia*, depending from an enabled base claim, claim 1.

Reconsideration and withdrawal of the written description rejection of claims 1-3 and 5 are respectfully requested.

Enablement

Claims 1-3 and 5 stand rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the enablement requirement. (*See*, Office Action, at pages 6-8). Applicants traverse the rejection as set forth herein.

The Examiner states that the claims "are rejected for the recitation of 'preventing.'" (*Id.* at page 7). The Examiner states that "it is not clear that reliance on the *in vitro* and *in vivo* experimental observations as well as the clinical experience with targeting a disorder resulting from release of CGRP with an antagonist of CGRP accurately reflects the relative ability or efficacy of the claimed methods to prevent psoriasis wherein the CGRP antagonist compound blocks binding of CGRP to its receptors is therapeutically beneficial." (*Id.*, *emphasis added*).

Although Applicants do not agree that the claims lack enablement, to expedite prosecution, claim 1 has been amended herein without prejudice or disclaimer to remove the term "preventing" from the claim.

Since no specific reasoning is provided for the enablement rejection of dependent claims 2, 3 and 5, these claims are believed to also be enabled as, *inter alia*, depending from an enabled base claim, amended claim 1.

Reconsideration and withdrawal of the enablement rejection of claims 1-3 and 5 are respectfully requested.

Rejections Under 35 U.S.C. § 102(b)

Claims 1-3 and 5 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Breton et al., U.S. Patent No. 6,019,967 (hereinafter, "Breton et al."). (*See*, Office Action, at pages 8-9). Applicants traverse the rejection as set forth herein.

The Examiner states that Brenton et al. disclose a method of treating psoriasis comprising administering topically or dermaly CGRP 8-37. (*Id.* at page 9).

However, the disclosure in Brenton et al. is extremely broad, prophetic, and clearly lacks enablement. For instance, the Examiner is respectfully referred to the recent legal precedent set forth in *Impax v. Aventis*, 468 F.3d 1366, Fed. Cir. 2006, which held: "In order to be anticipating, a prior art reference must be enabling so that the claimed subject matter may be made or used by one skilled in the art." (*See, Impax Laboratories Inc.,* 81 U.S.P.Q.2d 1001, 1011-1012, citing *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354, 65 U.P.S.Q.2d, 1385, (Fed. Cir. 2003)). The *Impax* court held that such vague, broad and generic disclosures of large genuses encompassing a myriad number of species are insufficient to form the basis of an anticipation rejection. (*See, Id.*, stating that when "a reference discloses a class of compounds, *i.e.*, a genus, a person of ordinary skill in the art should be able to 'at once envisage

each member of th[e] . . . class' for the individual compounds, *i.e.*, species, to be enabled," emphasis in original).

Furthermore, the Examiner is respectfully reminded that:

> "The single reference must describe and enable the claimed invention, including all claim limitations, with sufficient clarity and detail to establish that the subject matter already existed in the prior art and that its existence was recognized by persons of ordinary skill in the field of the invention."

(*See*, *Elan Pharmaceuticals Inc. v. Mayo Foundation for Medical Education and Research*, 64 U.S.P.Q.2d 1292, 1296 (Fed. Cir. 2002), citing *Crown Operations International, Ltd. v. Solutia Inc.*, 289 F.3d 1367, 1375, 62 U.S.P.Q.2d 1917, 1921 (Fed. Cir. 2002); and *In re Spada*, 911 F.2d 705, 708, 15 U.S.P.Q.2d 1655, 1657 (Fed. Cir. 1990)).

The present situation is much like that in *Impax*. That is, Breton et al. merely disclose a wish or desire, and a prophetic example, suggesting that perhaps any one of an extremely large number of extremely diverse compounds might somehow treat an equally long list of disparate diseases. Breton et al. do not clearly disclose a unifying mechanism or reasoning behind this conjecture. One of skill in the art would not rely on such hypothetical information to make and use an invention as presently claimed.

Breton et al. merely disclose the desire to treat anyone suffering from "sensitive skin" with the disclosed compounds. (*See*, Breton et al., at column 2, lines 63-65). The very large list of disorders to which the compositions are directed include, but are not limited to:

> insect bites, pain-relief compositions, compositions for treating acne, hyperseborrhoeic skin or seborrhoeic dermatitis, and compositions for treating certain skin diseases such as severe pruritus, rosacea, acne, leg ulcers, psoriasis, pustules and vibices ...

(*See*, *Id.* at column 4, lines 40-44). Breton et al. merely describe the use of a large, generically disclosed genus of CGRP antagonists, while only providing disclosure of two species within this large genus. (*Id.* at column 3, lines 65-67). As active ingredients, Breton et al. list an extremely large and diverse array of compounds, including, but not limited to:

> (1) Agents which modify cutaneous differentiation and/or proliferation and/or pigmentation such as retinoic acid and isomers thereof, retinol and esters thereof, vitamin D and derivatives thereof, estrogens such as estradiol, kojic acid or hydroquinone;
>
> (2) Antibacterial agents such as clindamycin phosphate, erythromycin or antibiotics from the tetracycline family;
>
> (3) Antiparasitic agents, in particular metronidazole, crotamiton or pyrethroids;
>
> (4) Antifungal agents, in particular compounds of the imidazole family such as econazole, ketoconazole or miconazole or salts thereof, polyene compounds such as amphotericin B, compounds of the allylamine family such as terbinafine, or alternatively octopirox;
>
> (5) Steroidal anti-inflammatory agents such as hydrocortisone, betamethasone valerate or clobetasol propionate, or nonsteroidal anti-inflammatory agents such as ibuprofen and salts thereof, diclofenac and salts thereof, acetylsalicylic acid, acetaminophen or glycyrrhetinic acid;
>
> (6) Anaesthetics such as lidocaine hydrochloride and derivatives thereof;
>
> (7) Antipruriginous agents such as thenaldine, trimeprazine or cyproheptadine;
>
> (8) Antiviral agents such as acyclovir;
>
> (9) Keratolytic agents such as alpha- and beta-hydroxycarboxylic acids or beta-ketocarboxylic acids, the salts, amides or esters thereof and more particularly hydroxy acids such as glycolic acid, lactic acid, salicylic acid, citric acid and fruit acids in general, and 5-n-octanoylsalicylic acid;
>
> (10) Anti-free-radical agents such as alpha-tocopherol or esters thereof, superoxide dismutases, certain metal chelating agents or ascorbic acid and esters thereof;
>
> (11) Antiseborrhoeic agents such as progesterone;
>
> (12) Antidandruff agents such as octopirox or zinc pyrithione;
>
> (13) Antiacne agents such as retinoic acid or benzoyl peroxide.

As these are listed as "active ingredients" by Breton et al., it is difficult to contemplate or even imagine the number of compositions encompassed by such a disclosure as is required to support an anticipation rejection based on a single reference. (*Id.* at columns 5-6).

Finally, Breton et al. provide no actual data. Although Breton et al. disclose several Examples, all of the Examples are simply compositions disclosing a list of ingredients and nothing more. (*Id.* at columns 8-9).

Thus, as a reference must provide an enabling disclosure to qualify as sufficient basis to establish anticipation, and since Breton et al. fail to provide an enabling disclosure for treatment of anything, using any particular compositions, Applicants assert that the Breton et al. disclosure fails to provide valid support for an anticipation rejection of the presently claimed invention.

Reconsideration and withdrawal of the anticipation rejection of claims 1-3 and 5 are respectfully requested.

CONCLUSION

If the Examiner has any questions or comments, please contact Thomas J. Siepmann, Ph.D., Registration No 57,374, at the offices of Birch, Stewart, Kolasch & Birch, LLP.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

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Respectfully submitted, #28977

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Attachments: Paper Copy of Substitute Sequence Listing (1 page)

CRF Copy of Substitute Sequence Listing